UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

April 13, 2020

MEMORANDUM

Subject: Efficacy Review for Ironman Wipe; EPA File No. 42182-RG; DP Barcode: D455646; Submission #: 1043818; E-Sub # 44720.

From: Ibrahim Laniyan, Ph.D.
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To: Jacqueline Hardy RM 34 / Stacey Grigsby
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Applicant: Microban Products Company
11400 Vanstory Drive
Huntersville, NC 28078

Formulation from the Label:

Active Ingredients	% by wt.
Ethanol	68.610 %
Alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride	0.276 %
Octyl decyl dimethyl ammonium chloride	0.207 %
Didecyl dimethyl ammonium chloride	0.104 %
Dioctyl dimethyl ammonium chloride	0.104 %
Other Ingredients:	30.699 %
Total	100.000 %

I. BACKGROUND

Product Description (as packaged, as applied): Towelettes

Submission type: New End-Product Registration

Currently registered efficacy claim(s): N/A

Requested action(s):
- Bacterial, viral, fungal, yeast, and mycobacterium disinfection.
- Non-food contact sanitization,
- Hard surface and fabric mildewstat claims
- Residual 24-hour disinfection
- Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels
- Bridging from Firebird F130, EPA Reg. No. 42182-9 to support additional bacterial, viral, and fungal disinfection claims. Some of these cited studies are already on file with EPA, others are currently under review for a label amendment for the source product. tin Willis confirmed the Agency
- Extension of the bridging policy to the residual disinfection claim category for any additional (nonrequired) bacteria.

Documents considered in this review:
- Letter from applicant to EPA dated (EPA form 8570-4) dated November 21, 2019
- Application for Pesticide (EPA form 8570-1) dated 11/21/2019
- Confidential Statement of Formula (EPA form 8570-4) dated 11/21/2019
- Formulator's Exemption Statement (EPA form 8570-27) dated 11/21/2019
- Data Matrix (EPA Form 8570-35) dated 11/21/2019
- Terms of Registration for Emerging Pathogens dated 10/30/2019
- 23 efficacy studies (MRID nos. 50974705 - 50974727)
- For Bridging, MRID nos. 50118922 – 50118928, 50118930, 50118932-50118938, 50118941, 50118942, 50118946, 50118947.
- Proposed label dated 11/21/19.

II. PROPOSED DIRECTIONS FOR USE

TO SANITIZE HARD, NONPOROUS, NONFOOD CONTACT SURFACES:
If present, use a wipe to remove visible soil prior to sanitizing. Unfold [a] [clean] wipe and thoroughly wet surface. Allow surface to remain wet for 10 seconds. Let air dry.

TO [CLEAN] [AND] [,] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES:
If present, use a wipe to remove visible soil prior to disinfecting. Unfold [a] [clean] wipe and thoroughly wet surface. Allow surface to remain wet [[for 5 [five] minutes][to disinfect bacteria, viruses, fungi, yeast, and Mycobacterium bovis BCG (TB) (at 73°F [23°C])]] [for 3 [three] minutes][to disinfect bacteria and viruses]] [[for 1 [one] minute][to disinfect bacteria and enveloped viruses]]. [Us [additional] [enough] wipe(s) [if needed,] to ensure surface is wet for contact time]. Let air dry. A potable water rinse is required for food contact surfaces.
[one of the contact time options above will be used as appropriate for the organisms listed on container label]

FOR CONTINUOUS DISINFECTION [OR RESIDUAL DISINFECTION] [OR CONTINUOUSLY ACTIVE DISINFECTION] ON HARD, NONPOROUS SURFACES FOR 24 HOURS:
If present, use a wipe to remove visible soil prior to disinfecting. Remove and unfold [a] [clean] wipe [from container]. Use wipe to [thoroughly] wet the surface to be disinfected. Ensure surface remains wet for 1 [one] minute to disinfect against the organisms in Table 4. Allow the surface to air dry for continuously active

disinfection up to 24 hours [with multiple touches]. Use of this product should not alter standard cleaning and disinfections practices. If the treated surface is cleaned, reapplication of product is necessary for continuous disinfection.

[Hard Surface Mildewstat] On hard surfaces:
[To inhibit mold and mildew growth]: If present, use a wipe to remove visible soil. Unfold [a] [clean] wipe and thoroughly wet surface. Let air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against Aspergillus brasiliensis [mildew]].

[Fabric Mildewstat] On fabric surfaces:
[To inhibit mold and mildew growth]: If present, use a wipe to remove visible soil. Unfold [a] [clean] wipe and thoroughly wet surface. [Do not saturate.] Let air dry. Repeat [application] every 28 days to inhibit mold [and mildew] growth. [Effective against Aspergillus brasiliensis and penicillium variabile[mildew]].

Emerging Viral Pathogen Claims
This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.
This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[y] [ies]:
• Enveloped Viruses: use Rotavirus, Strain WA (ATCC VR-2018)
• Large, Non-Enveloped Viruses: use Poliovirus type 1, Strain Chat (ATCC VR-1562) Or Feline Calicivirus, Strain F-9 (ATCC VR-782)
• Small, Non-Enveloped Viruses: use Poliovirus type 1, Strain Chat (ATCC VR-1562) Or Feline Calicivirus, Strain F-9 (ATCC VR-782)

III. STUDY SUMMARIES

1. MRID 509747-05, "Fungicidal Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Candida albicans* (ATCC 10231)" for Ironman Wipe; by Thomas Breyen. Study conducted at Accuratus Lab Services; Study completion date - October 17, 2019. Project No. A27647.

This study was conducted against *Candida albicans* (ATCC 10231). Two batches (181011-001 and 181206-001) of the product, Ironman Wipe, were tested using Accuratus Lab Services protocol no. SRC90032919.FTOW (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of 2 days culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 26.29 - 26.60°C, 64.19 - 68.46% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth three times for a total of 6 passes. The treated carriers were held for a 55 second exposure time at room temperature (18°C) and 40% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Sabouraud Dextrose Broth + 0.5% Tween 80. Each vessel was shaken thoroughly. All neutralized subcultures and plates were incubated for 46.25 hours at 29.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

2. MRID 509747-06, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Enterobacter aerogenes* (ATCC 13048)" for Ironman Wipe; by Kristin Hunt. Study conducted at Accuratus Lab Services; Study completion date - October 14, 2019. Project No. A28427.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). One batch (190610-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.10 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of 51 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.1-36.2°C, 50.1-51.2% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (20°C) and 45% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 46 hours at 29.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

3. MRID 509747-07, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Enterobacter aerogenes* (ATCC 13048)" for Ironman Wipe; by Kristin Hunt. Study conducted at Accuratus Lab Services; Study completion date - October 01, 2019. Project No. A28426.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). One batch (190607-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.11 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of 52 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.0-36.3°C, 50.1-53.2% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (20°C) and 44% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 46 hours at 29.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

4. MRID 509747-08, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Ironman Wipe; by Jamie Herzan. Study conducted at Accuratus Lab Services; Study completion date - October 16, 2019. Project No. A28393.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One batch (180914B-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.1 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 48 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.0-36.1°C, 52.7-62.8% relative humidity, until visibly dry; and were used within 2 hours

of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (20°C) and 49% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 46 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

5. MRID 509747-09, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Ironman Wipe; by Jamie Herzan. Study conducted at Accuratus Lab Services; Study completion date - October 07, 2019. Project No. A28394.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One batch (190607-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.2 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 51.5 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.1°C, 50.0-55.5% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (19°C) and 45% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 48.5 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

6. MRID 509747-10, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Ironman Wipe; by James Walrath. Study conducted at Accuratus Lab Services; Study completion date - October 10, 2019. Project No. A28428.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One batch (190610-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.3 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 52.5 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.1°C, 50.7-53.5% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (20°C) and 46% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 46.5 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

7. MRID 509747-11, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Staphylococcus aureus* (ATCC 6538)" for Ironman Wipe; by James Walrath. Study conducted at Accuratus Lab Services; Study completion date - October 22, 2019. Project No. A28439.

This study was conducted against *Staphylococcus aureus (ATCC 6538)*. One batch (180914B-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.7 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 48 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.1-36.2°C, 51.1-52.1% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (19°C) and 45% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 47 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

8. MRID 509747-12, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Staphylococcus aureus* (ATCC 6538)" for Ironman Wipe; by James Walrath. Study conducted at Accuratus Lab Services; Study completion date - October 22, 2019. Project No. A28440.

This study was conducted against *Staphylococcus aureus (ATCC 6538)*. One batch (190607-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.8 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 52 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.1-36.2°C, 51.6-52.8% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (20°C) and 51% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 47 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviation was reviewed.

9. MRID 509747-13, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Staphylococcus aureus* (ATCC 6538)" for Ironman Wipe; by Kristin Hunt. Study conducted at Accuratus Lab Services; Study completion date - October 01, 2019. Project No. A28425.

This study was conducted against *Staphylococcus aureus (ATCC 6538)*. One batch (190610-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.9 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 48 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at

36.1°C, 49.2-50.1% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (20°C) and 44% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 47.25 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

10. MRID 509747-14, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Salmonella enterica* (ATCC 10708)" for Ironman Wipe; by James Walrath. Study conducted at Accuratus Lab Services; Study completion date - October 10, 2019. Project No. A28436.

This study was conducted against *Salmonella enterica* (ATCC 10708). One batch (180914B-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.4 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 48 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.2-36.3°C, 56.1-60.0% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (19°C) and 52% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 47.5 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

11. MRID 509747-15, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Salmonella enterica* (ATCC 10708)" for Ironman Wipe; by James Walrath. Study conducted at Accuratus Lab Services; Study completion date - October 10, 2019. Project No. A28437.

This study was conducted against *Salmonella enterica* (ATCC 10708). One batch (190607-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.5 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 48.5 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.3°C, 51.2-56.2% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (19°C) and 52% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 47 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

12. MRID 509747-16, "Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Salmonella enterica* (ATCC 10708)" for Ironman Wipe; by James Walrath. Study conducted at Accuratus Lab Services; Study completion date - October 22, 2019. Project No. A28438.

This study was conducted against *Salmonella enterica* (ATCC 10708). One batch (190610-001) of the product, Ironman Wipe, was tested using Accuratus Lab Services protocol no. SRC90052819.TOW.6 (copy provided). The product lot tested was at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass carriers per product batch were inoculated with 10.0 µL of 51.5 hours culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 36.1-36.2°C, 50.3-56.5% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The treated carriers were held for a 55 second exposure time at room temperature (19°C) and 52% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Letheen Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All subcultures were incubated for 46.75 hours at 36.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

13. MRID 509747-17, "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus" for Ironman Wipe; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – September 19, 2019. Project Number A27557.

This study was conducted against F-9 strain of Feline Calicivirus (ATCC VR-782), using CRFK cells (Crandel Reese feline kidney cells, ATCC CCL-94) as the host system. Two lots (Lot Nos. 181011-001 and 181206-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90112718.FCAL (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50.0% relative humidity. For each lot of product, two dried virus films were individually wiped with one saturated towelette, and held covered at room temperature (22.0°C) for the 4.5-minute exposure time. Each carrier was divided into two sections and each section was treated by wiping the dried virus film with the towelette over and back three times for a total of six passes. At the end of the exposure time, a 2.00 ml aliquot of test medium was added to each petri dish, and the plates were individually scraped with a plastic cell scraper to re-suspend the contents (10^{-1} dilution). The virus-disinfectant mixture was passed through a Sephadex column (utilizing the syringe plungers), and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin and 2.5 µg/ml amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 33.0-33.1°C in a humidified atmosphere of 6.0-6.4% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.69 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.39 $\log_{10}$** for both batches.

14. MRID 509747-18, "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection: 2009-H1N1 Influenza A virus (Novel H1N1)" for Ironman Wipe; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – September 19, 2019. Project Number A27559.

This study was conducted against 2009-H1N1 Influenza A virus (Novel H1N1) Strain A/Mexico/4108/2009 (CDC # 2009712192), using MDCK cells (canine kidney, ATCC CCL-34) as the host system. Two lots (Lot Nos. 181011-001 and 181206-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90112718.FLUA (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 22.0°C for 20 minutes at 28.03% relative humidity. For each lot of product, one dried virus film was wiped with one saturated towelette, and held covered at room temperature (22.0°C) for the 10-second exposure time. Each carrier was divided into two sections and each section was treated by wiping the dried virus film with the towelette over and back three times for a total of six passes. At the end of the exposure time, a 2.00 ml aliquot of test medium was added to each petri dish, and the plates were individually scraped with a plastic cell scraper to re-suspend the contents (10^{-1} dilution). The virus-disinfectant mixture was passed through a Sephadex column (utilizing the syringe plungers), and diluted serially in Dulbecco's Modified Eagle Medium (D-MEM) supplemented with 2 µg/ml TPCK-trypsin, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 37°C in a humidified atmosphere of 6.0-6.4% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.30 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **5.50 $\log_{10}$** for both batches.

15. MRID 509747-19, "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection: Rotavirus, Strain WA (ATCC VR-2018)" for Ironman Wipe; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – September 19, 2019. Project Number A27558.

This study was conducted against Human Rotavirus, Strain WA (ATCC VR-2018), using MA-104 cells (Rhesus monkey kidney, ATCC CCL-2378.1) as the host system. Two lots (Lot Nos. 181011-001 and 181206-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90112718.ROT (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 22.0°C for 20 minutes at 40% relative humidity. For each lot of product, one dried virus film was wiped with one saturated towelette, and held covered at room temperature (22.0°C) for the 1.5-minute exposure time. Each carrier was divided into two sections and each section was treated by wiping the dried virus film with the towelette over and back three times for a total of six passes. At the end of the exposure time, a 2.00 ml aliquot of test medium was added to each petri dish, and the plates were individually scraped with a plastic cell scraper to re-suspend the contents (10^{-1} dilution). The virus-disinfectant mixture was passed through a Sephadex column (utilizing the syringe plungers), and diluted serially in Minimum Essential Medium (MEM) supplemented with 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, 0.5 µg/ml trypsin and 2.0 mM L-glutamine. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 37°C in a humidified atmosphere of 6.2-6.3% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **7.55 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **6.75 $\log_{10}$** for both batches.

16. MRID 509747-20, "Fungicidal Pre-Saturated Towelettes for Hard Surface Disinfection. Organism: *Trichophyton interdigitale* (ATCC 9533)" for Ironman Wipe; by Thomas Breyen. Study conducted at Accuratus Lab Services; Study completion date - September 19, 2019. Project No. A27636.

This study was conducted against *Trichophyton interdigitale* (formerly known as *T. mentagrophytes*) (ATCC 9533). Two batches (180914-001 and 181206-001) of the product, Ironman Wipe, were tested using Accuratus Lab Services protocol no. SRC90112718.FTOW (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of 10 days culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 40 minutes at 25.9 - 26.3°C, 53 - 63% relative humidity, until visibly dry; and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth three times for a total of 6 passes. The treated carriers were held for a 4.5-minute exposure time at room temperature (20°C) and 53% relative humidity in a horizontal and undisturbed fashion. Following exposure, individual carriers were drained and transferred to 20 mL Sabouraud Dextrose Broth + 0.28% Lecithin + 2.0% Tween 80. Each vessel was shaken thoroughly. All neutralized subcultures were incubated for 10 days at 29.0°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Testing performed on 5/10/2019 resulted in invalid data due to obtaining no growth in the Neutralization Confirmation Control subculture tubes. Testing was repeated on 6/25/2019, which resulted in invalid data due to a Carrier Population Control failure. Testing was repeated on 7/17/2019, which resulted in valid results presented in this review. Invalid results from testing performed on 5/10/2019 are presented in Attachment I and invalid results from testing performed on 6/25/2019 are presented in Attachment II.

Note: Protocol amendments were reviewed.

17. MRID 509747-21, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organisms: *Enterobacter aerogenes* (ATCC 13048)" for Ironman Wipe; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - September 26, 2019. Project No. A27775.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 180914-001, 181011-001, and 181206-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90051319.CUST.2.PROP, EPA Protocol 42182-PA-3 (copy provided). The product was received ready-to-use. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per product lot were treated (by wiping and ensuring the liquid expressed from the wipe did not spill over the glass panel edge) and allowed to dry uncovered at 21.8-23.0°C, 45-46% relative humidity in a humidity controlled chamber for 30 minutes, or until visually dry up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.0-36.1°C for 30 minutes under 50.3% RH, until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (18-19°C) and room humidity (52-54%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 22.0°C and 45-48% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes at 19°C and 50% RH, the carriers were transferred to 10 ml of Letheen Broth+ 0.28% Lecithin+ 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates

were incubated for 48.5hours at 29°C. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, purity, and neutralization.

18. MRID 509747-22, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organisms: *Pseudomonas aeruginosa* (ATCC 15442)" for Ironman Wipe; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - October 16, 2019. Project No. A27831.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 180914-001, 181011-001, and 181206-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90053119.CUST.PROP (EPA Protocol 42182-PA-3) (copy provided). The product was received ready-to-use. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per product lot were treated (by wiping and ensuring the liquid expressed from the wipe did not spill over the glass panel edge) and allowed to dry uncovered at 21.1-22.3°C, 46% relative humidity in a humidity controlled chamber for 30 minutes, or until visually dry up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.1°C for 30 minutes under 50.3% RH, until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (18-19°C) and room humidity (50-51%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 22.0-22.1°C and 45% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes at 20°C and 51% RH, the carriers were transferred to 10 ml of Letheen Broth+ 0.28% Lecithin+ 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48 hours at 36.0°C. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, purity, and neutralization.

19. MRID 509747-23, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organisms: *Staphylococcus aureus* (ATCC 6538)" for Ironman Wipe; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - October 16, 2019. Project No. A27877.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 180914-001, 181011-001, and 181206-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90051619. GUST. PROP, (EPA Protocol 42182-PA-3) (copy provided). The product was received ready-to-use. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per product lot were treated (by wiping and ensuring the liquid expressed from the wipe did not spill over the glass panel edge) and allowed to dry uncovered at 20.0-22.3°C, 45-46% relative humidity in a humidity controlled chamber for 30 minutes, or until visually dry up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.0-36.1°C for 30 minutes under 51.3-55.0% RH, until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (19-120°C) and room humidity (52-53%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 20.0-20.2°C and 45-48% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left

and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes at 19°C and 55% RH, the carriers were transferred to 10 ml of Letheen Broth+ 0.28% Lecithin+ 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48 hours at 36.0°C. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, purity, and neutralization.

Note: Testing started 6/13/19 resulted in carrier population control failure and invalid data (geometric mean of 7.94×10^5 CFU/carrier which was below the acceptance criteria of 1×10^6 CFU/carrier). The entire test was repeated, starting on 6/27/19, and resulted in valid data presented in this review. Invalid data can be found in Attachment I.

Note: Protocol deviation was reviewed.

20. MRID 509747-24, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Product Application). Organism: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538)" for Ironman Wipe; by Jamie Herzan. Study conducted at Accuratus Lab Services; Study completion date - October 07, 2019. Project No. A28401.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (190607-001, 190610-001, and 180914B-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services protocol no. SRC90052819.NFS (copy provided). The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Five (5) glass carriers (1 inch x 1 inch) per product lot were inoculated with 0.02 mL of a 53 hour culture/soil suspension of the test organism. The carriers were dried for 20 minutes at 36.0-36.1°C and 41-43% relative humidity with the Petri dish lids slightly ajar. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. Carriers were allowed to expose at room temperature (20˚C) and 45% relative humidity for 10 seconds. Following exposure, each carrier was transferred to 20 mL of D/E Neutralizing Broth; the excess liquid in each Petri dish was transferred to the neutralizer jar containing the matching carrier. The carriers were vortex-mixed for 10-15 seconds to ensure complete elution of the test organism. Within 30 minutes of neutralization, duplicate 1.0 ml and 0.1 ml aliquots of the neutralized solution (10^0) were plated onto Tryptic Soy Agar with 5% Sheep Blood. The culture/control medium plates were incubated for 44.5 hours for at 36.0°C *(S. aureus)* and 29.0°C (*E. aerogenes)*. Following incubation the subcultures were visually enumerated. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

21. MRID 509747-25, "EPA Hard Surface Mildew-Fungistatic Test. Organism: *Aspergillus niger* (ATCC 6275)" for Ironman Wipe; by Kristin Hunt. Study conducted at Accuratus Lab Services; Study completion date – October 14, 2019. Project No. A27625.

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (Lot Nos. 181011-001 and 181206-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90112718.MSTAT (copy provided). The product was received. A conidial suspension of a 10 days old culture containing 5% fetal bovine serum was used. Ten sterile 1 x 1" glazed ceramic tiles per lot were treated with the towelette by wiping over and back three times for a total of six passes per surface. Then, excess liquid was allowed to drain off. The carriers were dried in empty Petri dishes with the lids ajar at 36.1°C for 38 minutes and at 39-41% relative humidity. Untreated glazed tiles were also held under the same conditions, alongside the test carriers. Following the drying period, the surfaces of each test tile and each control tile were sprayed (3X) with the conidial suspension using a DeVilbiss #152 atomizer. The tiles were returned to 36.1°C and dried for 38 minutes at 40-41% relative humidity, until visibly dried. Each tile (treated side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 29°C in a minimum of 95% relative humidity. When no

growth was visually observed, a magnified examination was performed. Controls included those for purity and sterility. The reported growth percentages on **untreated control tiles range from 70% to 90%**.

22. MRID 509747-26, "Fabric Mildew Fungistatic Test. Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333)" for Ironman Wipe; by Jamie Herzan. Study conducted at Accuratus Lab Services; Study completion date - September 26, 2019. Project No. A27755.

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333). Two lots (Lot Nos. 150409-001 and 150611-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90042419.FMSTAT [as published in EPA's Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 1: Fabric Mildew Fungistatic Test Method, November 1982)] (copy provided). The product was received ready-to-use. Conidial suspensions prepared from of a 10 days old culture (*A. niger*) and 7 days old culture (*P. variabile*), containing 5% fetal bovine serum, were used. Upon maturity, the spores were removed, and the suspensions were filtered through sterile cotton to remove the hyphae and hyphal fragments. Strips measuring 25 x 75 mm each were cut from unbleached cotton fabric. Each strip weighed 136 to 203 g/m^2 (to conform to the EPA guidelines). All strips were autoclaved, with a subsequent soak in glycerol nutrient solution for 3 minutes. Each fabric strip was dried under sterile conditions before use. Ten dried, nutrient saturated fabric strips per lot were evaluated. For each batch of test substance, both sides of 10 test carriers were treated with the towelette by wiping the carriers with 2-3 passes, until thoroughly wet (carriers 1-5 were wiped with 2 passes and carriers 6-10 were wiped with 3 passes). The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. The strips were hung in the sterile laminar air flow hood. Ten untreated fabric strips were sprayed with saline solution in place of the test agent for the untreated control. All samples were dried for 11 minutes at room temperature (22.73-22.91°C) and at a 36.64-37.88% relative humidity, until dry; before inoculation. Equal volumes suspension of *A. niger* and *P. variabile* were mixed together, agitated, and adjusted to have 5% organic soil. Each side of each fabric strips was lightly sprayed to inoculate the mixed conidial suspension using a DeVilbiss atomizer (2 sprays). The fabric samples were suspended in individual 250 ml French Square bottles containing approximately 10 ml sterile deionized water and incubated at 29°C. Observations were made and recorded weekly for 4 weeks (minimally 7, 14, 21 and 28 days). The presence or absence of observable mold on the fabric strips was the criterion for determining the efficacy of the test agent. When no visible growth was evident at the end of the test period, the fabric strips were examined microscopically. Controls included those for purity and sterility.

23. MRID 509747-27, "AOAC Tuberculocidal Activity of Disinfectant Towelette Products. Organism: *Mycobacterium bovis* (ATCC 35743)" for Ironman Wipe; by Rick Shimshock. Study conducted at Accuratus Lab Services; Study completion date – November 12, 2019. Project No. A28322.

This study was conducted against *Mycobacterium bovis* (ATCC 35743). Two batches (190610-001 and 190607-001) of the product, Ironman Wipe, were tested according to Accuratus Lab Services Protocol No. SRC90051519.TB.2 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use towlette. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of standardized 20-days culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 30 minutes at 36.1°C and at 52.3-52.6% relative humidity, and were used within 2 hours of drying. One towelette was used to wipe the contaminated portions of 10 carriers. The area of the towelette used was rotated so as to expose a maximum amount of the towelette surface during the course of the wiping procedure. Each inoculated carrier was treated with the towelette by passing over the carrier surface back and forth 2.5 times for a total of 5 passes. The carriers were exposed for 4 minutes 45 seconds at 22.83°C and 44.35% relative humidity. Following exposure, individual carriers were drained and transferred to 20 mL Horse Serum+ 0.5% Lecithin+ 0.25% Tween 80. The vessel containing the carrier in neutralizer was shaken and then after 5-10 minutes, the carrier was transferred to a vessel containing 20 ml of Modified Proskauer-Beck

Broth. Within approximately 30 minutes of neutralization, a 2.0 ml aliquot of the neutralizer was transferred to individual vessels containing 20 ml of Middlebrook 7H9 Broth and 20 ml of Kirchner's Medium. Each subculture vessel was shaken thoroughly. All subculture broths were incubated at 36.0°C under aerobic conditions. The subcultures were visually examined for growth following a 30 and 62 days incubation period. All test subcultures demonstrated a lack of growth of the test organism therefore the subcultures were incubated an additional 28 days and re-examined. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

V. RESULTS

MRID Number	Organism	No. Carriers Exhibiting Growth/Total					Carrier Population (log_{10})
		180914-001 or 180914B-001	181011-001	181206-001	190607-001	190610-001	
RTU Towelettes – 5% serum – 55 seconds contact time – Ambient room temperature							
509747-05	*Candida albicans* (ATCC 10231)	-	0/10	0/10	-	-	6.66
509747-06	*Enterobacter aerogenes* (ATCC 13048)	-	-	-	-	0/10	4.15
509747-07	*Enterobacter aerogenes* (ATCC 13048)	-	-	-	0/10	-	4.25
509747-08	Pseudomonas aeruginosa (ATCC 15442)	0/60	-	-	-	-	5.82
509747-09	Pseudomonas aeruginosa (ATCC 15442)	-	-	-	0/60	-	5.26
509747-10	Pseudomonas aeruginosa (ATCC 15442)	-	-	-	-	0/60	5.42
509747-11	*Staphylococcus aureus* (ATCC 6538)	0/60	-	-	-	-	5.81
509747-12	*Staphylococcus aureus* (ATCC 6538)	-	-	-	0/60	-	5.84
509747-13	*Staphylococcus aureus* (ATCC 6538)	-	-	-	-	0/60	5.83
509747-14	*Salmonella enterica* (ATCC 10708)	1/60	-	-	-	-	5.45
509747-15	*Salmonella enterica* (ATCC 10708)	-	-	-	0/60	-	5.13
509747-16	*Salmonella enterica* (ATCC 10708)	-	-	-	-	0/60	5.14
RTU Towelettes – 5% serum – 4.5 minutes contact time – Ambient room temperature							
509747-20	*Trichophyton interdigitale* (ATCC 9533)	0/10	-	0/10	-	-	4.83

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/Carrier)
			181011-001	181206-001	
RTU Towelettes – 5% serum – 4.5-minute contact time – Ambient room temp (20ºC).					
509747-17	Feline Calicivirus (ATCC VR-782)	10^{-1} dilution	Viral Activity	Viral Activity	$10^{5.69}$
		10^{-2} to 10^{-4} dilutions	Inactivity	Inactivity	
		$TCID_{50}$/Carrier	$10^{1.30}$	$10^{1.30}$	
		Log reduction	4.39 $\log_{10}$	4.39 $\log_{10}$	
RTU Towelettes – 5% serum – 10 sec. contact time – Ambient room temp (22ºC).					
509747-18	2009-H1N1 Influenza A virus (Novel H1N1) Strain A/Mexico/4108/2009 (CDC#2009712192)	10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.30}$
		$TCID_{50}$/Carrier	$\leq 10^{0.80}$	$\leq 10^{0.80}$	
		Log reduction	≥5.50 $\log_{10}$	≥5.50 $\log_{10}$	
RTU Towelettes – 5% serum – 1.5 min. contact time – Ambient room temp (22ºC).					
509747-19	Rotavirus, Strain WA (ATCC VR-2018)	10^{-1} to 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{7.55}$
		$TCID_{50}$/Carrier	$\leq 10^{0.80}$	$\leq 10^{0.80}$	
		Log reduction	≥6.75 $\log_{10}$	≥6.75 $\log_{10}$	

MRID Number	Carrier Type	Lot No.	CFU/Carrier Average Log_{10}	Percent Reduction	Carrier Population (log_{10} CFU/Carrier)	
					Non-Abrasion	Abrasion
RTU Towelettes – 5% serum – 4.5 min. contact time – Ambient room temp						
509747-21	*Enterobacter aerogenes* (ATCC 13048)	180914-001 181011-001 181206-001	<1.00 <1.00 <1.00	>99.999% >99.999% >99.999%	6.46	6.15
509747-22	*Pseudomonas aeruginosa* (ATCC 15442)	180914-001 181011-001 181206-001	<1.00 <1.00 <1.08	>99.999% >99.999% >99.999%	6.40	6.37
509747-23	*Staphylococcus aureus* (ATCC 6538)	180914-001 181011-001 181206-001	<1.00 <1.00 <1.00	>99.999% >99.999% >99.999%	6.76	6.80

MRID Number	Organism	Lot No.	CFU/Carrier Average Log_{10}	Percent Reduction	Carrier Population (Log_{10} CFU/Carrier)
509747-24	*Enterobacter aerogenes* (ATCC 13048)	190607-001 190610-001 180914B-001	<1.30 <1.30 <1.30	>99.999% >99.999% >99.999%	6.38
	Staphylococcus aureus (ATCC 6538)	190607-001 190610-001 180914B-001	<1.30 <1.30 <1.30	>99.99% >99.99% >99.99%	6.24

MRID # 509747-25	Lot #	7-day Evaluation	Evaluation of Test Carriers (percent %)									
			1	2	3	4	5	6	7	8	9	10
	Control	Visual	70	70	80	70	70	80	90	80	80	70

Aspergillus niger (ATCC 6275)	181011-001	Visual	0	0	0	0	0	0	0	0	0	0
		Magnified	-	-	-	-	-	-	-	-	-	-
	181206-001	Visual	0	0	0	0	0	0	0	0	0	0
		Magnified	-	-	-	-	-	-	-	-	-	-

MRID # 509747-26	**Visual Evaluation of Control Carriers**	**Evaluation of Test Carriers (percent %)**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Aspergillus niger (ATCC 6275) and *Penicillium variabile* (ATCC 32333)	7 Days	90	60	85	85	90	100	95	90	90	85
	14 Days	90	60	90	85	95	100	95	90	90	90
	21 Days	90	60	90	85	95	100	95	90	90	90
	28 Days	90	60	95	85	100	100	100	90	90	90

Organisms	**Lot #**	**Evaluation of Test Carriers 1 to 10 (percent %)**							
		Day 7		**Day 14**		**Day 21**		**Day 28**	
		Visual	**Magnified**	**Visual**	**Magnified**	**Visual**	**Magnified**	**Visual**	**Magnified**
A niger and *P. variable*	181011-001	0	0	0	0	0	0	0	0
	181206-001	0	0	0	0	0	0	0	0

MRID # 509747-27	**Lot #**	**Subculture Medium**	**Number of carrier showing growth/Exposed**			**Average (log_{10})**
			Day 30	**Day 62**	**Day 90**	
Mycobacterium bovis - BCG	**190607-001**	MPB	0/10	0/10	0/10	5.24
		7H9	0/10	0/10	0/10	
		KM	0/10	0/10	0/10	
	190610-001	MPB	0/10	0/10	0/10	
		7H9	0/10	0/10	0/10	
		KM	0/10	0/10	0/10	

VI. CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support Label Claims?
509747-06 509747-07 509747-08 509747-09 509747-10 509747-11 509747-12 509747-13 509747-14 509747-15 509747-16	**Disinfectant Bactericidal**	Hard, non-porous surfaces	RTU Towelettes Wiping	55 sec.	5% FBS	No	*Enterobacter aerogenes* (ATCC 13048) *Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538) *Salmonella enterica* (ATCC 10708)	**Yes**
509747-05 509747-20	**Disinfectant Fungicidal**	Hard, non-porous surfaces	RTU Towelettes Wiping	55 sec.	5% FBS	No	*Candida albicans* (ATCC 10231) *Trichophyton interdigitale* (ATCC 9533)	**Yes**
509747-20	**Disinfectant Fungicidal**	Hard, non-porous surfaces	RTU Towelettes Wiping	4.5 min.	5% FBS	No	*Trichophyton interdigitale* (ATCC 9533)	**No Because label has 3 min. contact time**
509747-17	**Disinfectant Virucidal**	Hard, non-porous surfaces	RTU Towelettes Wiping	4.5 min.	5% serum	No	Feline Calicivirus (ATCC VR-782)	**Yes**
509747-18	**Disinfectant Virucidal**	Hard, non-porous surfaces	RTU Towelettes Wiping	10 sec.	5% serum	No	2009-H1N1 Influenza A virus (Novel H1N1) Strain A/Mexico/4108/2009 (CDC #2009712192)	**Yes**
509747-19	**Disinfectant Virucidal**	Hard, non-porous surfaces	RTU Towelettes Wiping	1.5 min.	5% serum	No	Rotavirus, Strain WA (ATCC VR-2018)	**Yes**
509747-21 509747-22 509747-23	**Residual Bactericidal Disinfection**	Hard, non-porous surfaces	RTU Towelettes Wiping	4.5 min.	5% FBS	No	*Enterobacter aerogenes* (ATCC 13048) *Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538)	**Partially Yes Need contact time of at least 4.5 min. to be on label**
509747-24	**Non-Food Contact Sanitization**	Hard, non-porous surfaces	RTU Towelettes Wiping	10 sec.	5% FBS	No	*Enterobacter aerogenes* (ATCC 13048) *Staphylococcus aureus* (ATCC 6538)	**Yes**
509747-25	**Hard Surface Mildew-Fungistatic**	Hard, non-porous surfaces	RTU Towelettes Wiping	7 days.	5% FBS	No	*Aspergillus niger* (ATCC 6275)	**Yes**
509747-26	**Fabric Mildew Fungistatic**	Fabric	RTU Towelettes Wiping	28 Days	5% FBS	No	*Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333)	**No Inappropriate use of towelettes**
509747-27	**Disinfectant Tuberculocide**	Hard, non-porous surfaces	RTU Towelettes Wiping	4 min. 45 secs.	5% FBS	No	*Mycobacterium bovis* (ATCC 35743).	**Yes**

VII. LABEL COMMENTS

Proposed Label dated 11/21/2019

1. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective disinfectant towelettes, against 2009-H1N1 Influenza A virus (Novel H1N1) Strain A/Mexico/4108/2009 (CDC #2009712192), at room temperature, for at least 10-seconds contact time, on visibly clean hard, non-porous surfaces; **are acceptable**.

2. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective disinfectant towelettes, against the following microorganisms, at room temperature, for at least 1-minute contact time, on visibly clean hard, non-porous surfaces; **are acceptable**.

- *Enterobacter aerogenes* (ATCC 13048)
- *Pseudomonas aeruginosa* (ATCC 15442)
- *Staphylococcus aureus* (ATCC 6538)
- *Salmonella enterica* (ATCC 10708)
- *Candida albicans* (ATCC 10231)

3. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective disinfectant towelettes, against Rotavirus, Strain WA (ATCC VR-2018), at room temperature, for at least 2-minute contact time, on visibly clean hard, non-porous surfaces; **are acceptable**.

4. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective disinfectant towelettes, against *Trichophyton interdigitale* (ATCC 9533), at room temperature, for at least 3-minute contact time, on visibly clean hard, non-porous surfaces; **are not acceptable**. **The submitted efficacy study was conducted at 4.5 minutes contact time. Registrant must change contact time on the label to at least 4.5 minutes to keep claims for *Trichophyton interdigitale*.**

5. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective disinfectant towelettes, against the following microorganisms at room temperature, for at least 5-minutes contact time, on visibly clean hard, non-porous surfaces; **are acceptable**.

- Feline Calicivirus (ATCC VR-782) (surrogate for Norovirus)
- *Mycobacterium bovis* (ATCC 35743)

6. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), when used to treat visibly clean hard non-porous surfaces, and the released liquid on surfaces is allowed to air dry, it confers a residual disinfecting activity that can last 24 hours for the following microorganisms, at room temperature; **are partially acceptable**. **The registrant failed to add at least 4.5 minutes contact time necessary to residually disinfect surfaces in the absence of visible soil.**

- *Enterobacter aerogenes* (ATCC 13048)
- *Pseudomonas aeruginosa* (ATCC 15442)
- *Staphylococcus aureus* (ATCC 6538)

Claims will be acceptable when, necessary 5-minutes contact time for effective residual disinfection activity, in the absence of visible soil, will be added to the label claims (not to be optional claims).

7. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective non-food contact surface sanitizer towelettes, against the following microorganisms, at room temperature, for at least 10-seconds contact time, on visibly clean hard, non-porous surfaces; **are acceptable**.

- *Enterobacter aerogenes* (ATCC 13048)
- *Staphylococcus aureus* (ATCC 6538)

8, The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective 7-days mildew fungistatic towelettes product, against *Aspergillus niger* (ATCC 6275), when used to treat visibly clean hard non-porous surfaces, at room temperature, **are acceptable**.

9. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), is an effective 28-days mildew fungistatic towelettes product, when used to treat visibly clean fabric surfaces, at room temperature, **are not acceptable**. **Remove all fabric mildew fungistatic claims from the label**.

Towelette application is not appropriate for fabrics treatment.
Reported fungus growth on some carriers is not reflecting of growth pattern expected between 7 and 28 days

10. The proposed label claims that the product, Ironman Wipe (EPA File No. 42182-RG), qualifies for the following emerging viral pathogens claims as described:

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Rotavirus, Strain WA (ATCC VR-2018)
Large, non-enveloped virus	Poliovirus type 1, Strain Chat (ATCC VR-1562) Or Feline Calicivirus, Strain F-9 (ATCC VR-782)
Small, non-enveloped virus	Poliovirus type 1, Strain Chat (ATCC VR-1562) Or Feline Calicivirus, Strain F-9 (ATCC VR-782)

These claims are **partially acceptable**. Until bridging is acceptable (See Comment 11 below), Poliovirus must be removed from the label and "Terms of Registration"; so small, non-enveloped virus claims cannot be made.

Please make the following changes to the Terms of Registration. Note that there should not be any specific mention of SARS-CoV-2 on the Terms of Registration:

- Revise the "Terms of Registration" letter per the attached "template":
  - Insert the product name where applicable in the in the language under "Statements will adhere to one or both of the following formats".
  - Add numbers/letters (see template) including the three line items referred to in the next to last paragraph.
  - On the line item No. 3 revise the statement "The registrant (Microban) may begin communicating these statement(s) upon notification on the CDC or OIE website identified under Section V of the Guidance of an outbreak of an emerging **enveloped** viral pathogen." to "The registrant (Microban) may begin communicating these statement(s) upon notification on the CDC or OIE website identified under Section V of the Guidance of an outbreak of an emerging **large non-enveloped and/or** enveloped viral pathogen."

Revise the emerging viral pathogens statement on page 15 of the label exactly as follows. Note that there should not be any specific mention of SARS-CoV-2 on the master label:
"This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses
-Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Rotavirus, Strain WA (ATCC VR-2018)
Large, non-enveloped virus	Feline Calicivirus, Strain F-9 (ATCC VR-782)

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information."

11. **The following claims from Firebird F130, EPA Reg. No. 42182-9 cannot be bridged to the towelette product Ironman Wipe (EPA File No. 42182-RG) because, analytical data for the active ingredients, in towelettes expressed liquid, compared to the bulk liquid used to make them (the towelettes), were not submitted as a study for review:**

Disinfection activities

- *Acinetobacter baumannii* MDR (Multi-drug resistant) [ATCC BAA-1605]
- *Escherichia coli* ESBL (Extended spectrum beta-lactamase) [ATCC BAA-196]
- *Escherichia coli* O157:H7 [ATCC 35150]
- *Enterobacter aerogenes* MDR (Multi-drug Resistant) [ATCC 29751]
- *Enterococcus faecalis* VRE (Vancomycin resistant enterococcus) [ATCC 51575]
- *Enterococcus faecium* MDR (Multidrug Resistant) [ATCC 51559]
- *Klebsiella pneumoniae* CRE (Carbapenem resistant Enterobacteriaceae) [ATCC BAA-2146]
- *Pseudomonas aeruginosa* MBL (Metallo beta-lactamase positive) [CDC AR-0246/PSA-18]
- Staphylococcus aureus (Methicillin Resistant) (MRSA) [ATCC 33592]
- *Staphylococcus aureus* (VISA) (Vancomycin-Intermediate) [HIP5836]
- *Staphylococcus aureus* (VRSA) (Vancomycin-Resistant) [HIP11714]
- *Staphylococcus epidermidis* (Methicillin Resistant) (MRSE) [ATCC 51625]

- Avian Influenza A (H3N2) Reassortant virus [ATCC VR-2072] [A/Washington/897/80 x A/Mallard/New York/6750/78]
- Hepatitis B Virus (HBV) (Duck Hepatitis B Virus [as surrogate]) [11/4/12]
- Hepatitis C Virus (HCV) (Bovine Viral Diarrhea Virus [as surrogate]) [Oregon C24v-genotype 1]
- Herpes simplex virus type 1 [ATCC VR-733] [F(1)]
- Herpes simplex virus type 2 [ATCC VR-734] [G]
- Human Coronavirus [ATCC VR-740] [229E]
- Human Immunodeficiency virus type 1 (HIV) [HTLV-IIIB]

- Respiratory syncytial virus (RSV) [ATCC VR-26] [Long]
- 2009-H1N1 Influenza A virus (Novel H1N1) [CDC 2009712192] [A/Mexico/4108/2009]
- Poliovirus type 1 [ATCC VR-1562] [Chat]

- Aspergillus niger [ATCC 6275]

Residual disinfection activities
- *Acinetobacter baumannii* MDR (Multidrug resistant) [ATCC BAA-1605]
- *Enterobacter aerogenes* MDR (Multidrug Resistant) [ATCC 29751]
- *Enterococcus faecalis* VRE (Vancomycin resistant enterococcus [ATCC 51575]
- *Enterococcus faecium* MDR (Multidrug Resistant) [ATCC 51559]
- New Delhi metallo-beta-lactamase-1 (NDM-1) producing *Klebsiella pneumoniae* (CRE - Carbapenem resistant Enterobacteriaceae) [ATCC BAA- 2146]
- *Staphylococcus aureus* (Methicillin Resistant) (MRSA) [ATCC 33592]

These organisms and all claims related them must be removed from the label until bridging argument study is submitted for review and is acceptable.

12. Registrant must make the following additional changes to the proposed label:

- Throughout the label:
    - Remove all claims of effectiveness against “cold” and/or “cold and flu” virus, until the “bridging argument study is submitted for review and accepted” (See comment No. 11 above).
    - Remove claims against “ESKAPE organisms/pathogens until comment No. 11 (above) has been addressed.
    - Delete or qualify the terms “eradicate(s)” and/or “eliminate(s)” when used to describe efficacy in public health claims language. The registrant can qualify with the appropriate removal % as demonstrated by the submitted data.
- On page 20, under Residual Disinfection, remove “First” because it is misleading
- On page 22, remove “[and 7-day mold & mildew prevention] [even after multiple touches]” because residual disinfection study was not conducted on mold and mildew; and it is limited to 24 hours claim.